FINAL REPORT
FINALIZATION OF COSMETIC GMP DRAFT MODULES AND ON-SITE AUDIT
14-19 November 2005, Kuala Lumpur Malaysia

INTRODUCTION

The Cosmetic GMP Finalization of draft modules and on-site audit was held in Sheraton Hotels and Towers Ballroom at Subang Jaya, Malaysia last November 14-19.

The meeting was chaired by the ASEAN Senior Expert from the Lead Country, Mr. Mohammad. Lukmani Ibrahim. Co-Chaired by Ms. Nuning Barwa and Ms. Pia Rose Belarmino, the 2 other senior experts from Indonesia and Philippines respectively.

The Meeting was attended by the ACC head of delegates from Brunei Darussalam, Mr. Chong Chee Kiong; Cambodia, Mr. Chieng Phana; Indonesia, Ms. Hayatie Amal; Lao PDR, Mr. Vongtavanh Cheimsisourath; Malaysia, Ms. Anis Talib; Singapore, Ms. Marie Tham; Thailand, Ms. Yupa Tiengthavaj; and Vietnam, Ms. Ta Thi Phuc Chan, GMP taskforce (18), 6 additional NRA , and representatives from the national regulatory agency of Malaysia as observers. The list of delegates appears as annex 1 of this report.

OPENING CEREMONIES

The Deputy Director of the National Pharmaceutical Bureau of Malaysia, Puan Yogeswary Markandoo opened and welcomed the ACC Head of Delegates, GMP Taskforce, Senior Experts and the national regulatory authority participants on the 3-day finalization of draft training modules. She thanked everyone for the hard-work they gave and for coming out of this training module which will give and provide a standard interpretation of GMP. She congratulated the team for making a dream come into reality. She encouraged everyone to continue practicing GMP as their way of life.

In behalf of the CEN Team Leader, Mr. Alain Decharnat, the ASEAN Officer welcomed everyone to the workshop. He reminded everyone the importance of the output of this workshop and expressed appreciation for the efforts done by the GMP task force.

The chair of the meeting greeted everyone and explained the process of the meeting. As the ACC Chair and co-chair were not present, the meeting agreed to adopt in principle the training modules and will endorse to ACC meeting for the official adoption in the Brunei meeting on December 6-8.

MEETING PROPER

AGENDA ITEM 1. Presentation and finalization of Module #1 Quality Management System

Module authored by Davong Oumavong (Laos), and Ms. Hui Foong Mei (Singapore). Presented by Ms. Hui Foong Mei in the meeting.

Corrections agreed:

Slide # 3 Bullet 1 - Objectives - instead of to understand key issues in quality management, quality assurance, GMP and quality control:
➢To understand key concepts of quality management, quality assurance, GMP and quality control.

Slide # 5 Bullet 2 – Basic Principles of QM - instead of They should also comply with any other applicable regulations:
➢They should also comply with any other applicable regulations pertaining to your specific country.

Slide # 13 Bullet 3 – Basic Requirements of QC - instead of Validated Test Methods:
➢Approved test methods

Slide # 25 Tiers of Documentation - instead of Broadly, all documents relating to quality fall into the following categories :
Broadly, all documents relating to quality fall into the following categories should be controlled:

Slide # 42 Quality Manual Contents Equipment -instead of Describe the requirements of the design, installation and maintenance of the equipment and its support system such as HVAC, water:
Describe the requirements of the design, installation and maintenance of the equipment and its support system such as ventilation system and water.

AGENDA ITEM 2. Presentation and finalization of Module #2 Personnnel

Module authored by Ms. Rosni Jair (Brunei) presented by Wan Othman Wan Ismail (Malaysia)

Corrections agreed:

Slide # 9 Bullet 2 Key Personnel - instead of Head Of Quality Control:
➢Head of Quality Control/Head of Quality Assurance

Deleted bullet #3 – Head of Sales and distribution

Slide #10 deleted Practical experience thus:

•Key personnel should be appropriately qualified and/or possess adequate practical experience
• Examples of desirable qualifications include:
- chemistry, biochemistry, chemical engineering, microbiology, pharmaceutical sciences and technology, pharmacology and toxicology, physiology; or
- other related science or GMP-related subjects relevant to the responsibilities to be undertaken

Slide # 17 Shared Responsibilities - add in the last bullet:
➢Corrective and preventive action

Slide # 19 Examples of Organizational Chart - last box to the right instead of IPQI

All agreed to change to IPQC

Slide # 26 Personnel Hygiene - instead of Avoid direct contact of operator's hands and products including starting/ packaging materials:

Avoid direct contact of operator's hands and products including starting/ packaging materials and surfaces of equipment that come in direct contact with the product

AGENDA ITEM 3. Presentation and finalization of Module #3 Premises

Module authored and presented in the meeting by Mr. Niphon Phaonimmongkol (Thailand).

Corrections agreed:

Slide # 7 Defined Areas - instead of Receiving of starting and packaging materials:

Changed to: Loading and Unloading

Slide #10 Materials and construction -add in, or equivalent after resin finish, thus:

Solid concrete with epoxy or polyurethane resin finish, or equivalent, is suitable for processing areas as it has a non-porous topping with non skid surface & retards bacterial growth.

Slide # 13 Loading and Unloading -instead of receiving/dispatch:

Loading and Unloading

Slide 24 Equipment Washing - to add narrative form for the picture, thus:

Area for equipment washing must be provided with adequate drainage system and proper storage of cleaning equipment should be observed.

Slide 26 Staging of Bulk/Packaging Materials - to add narrative form for the picture, thus:

Staging of bulk/packaging materials (not including tertiary corrugated boxes) should be properly stored in separate areas. Corridors may be used provided that storage is temporary and sufficient control is demonstrated such as flow of traffic is not hindered, bulk should be properly labeled and sealed.

Previous Slides # 33, 34, and 35 Mechanics of an airconditioning Unit

Corrections agreed: Deleted the slides

Slide 37 Contamination - leaking lubricant, spillage example in bullet 1, - dragged to chemical example and add rust
-second bullet add examples of chemicals thus:

1.Physical – e.g. dust, rust
2.Chemical – e.g. leaking lubricants, spillage, previous product, wrong materials and any other chemicals outside product formulation.

Slide 40 Flow Chart - Add explanation of the flow, thus:

Explanation were given below the slide as notes.

AGENDA ITEM 4 . Presentation and finalization of Module #4 Equipment Module authored and presented in the meeting by Surachai Piyayodilokchai (Thailand).

Corrections agreed:

Slide 10 Basic requirements - 4th Bullet add malfunctioning of equipment, thus:

Where deviations from product specifications could occur as the result of malfunctioning of equipment(s), the manufacturer shall establish and maintain process control procedures.

Previous Slide # 11 Equipment Selection - Corrections agreed:

Deleted the whole slide, with all hyperlink

Previous Slide # 12 Equipment Qualification - Corrections agreed:

Deleted Slide

Slide # 17 Pipes and Pipelines -add the slide with pictures

Slide # 26 Equipment Cleaning - picture shown should have explanation, thus:

Cleaning Protocol for trace back record
Cleaning status of the equipment should be indicated on the label

To add the following slides with pictures:

Slides 20 Location and Installation
Slide 22 Flexible Hoses
Slide 23 Types of Materials Used
Slide 24 Types of Materials Used
Slide 17 Pipes and Pipelines

Slide # 28 Calibration - corrections agreed:

2nd and 3rd bullet is deleted from the slide but added in the notes.

Slide # 30 Change Control - changed to:

Bullet #1 Change the word separated to classified

Bullet # 2 Where intended changes are to be made, corrective actions must be defined before there implementation for the first 3 groups. The other 2 groups which are unplanned cases need to provide proper documentation.

Previous Slide # 28 - corrections agreed to delete

Slide # 31 Training Program - Corrections agreed to delete 3rd bullet

AGENDA ITEM 5. Presentation and Finalization of Module # 5 Sanitation and Hygiene
Module authored and presented in the meeting by Ms. Ofelia Malagkit (Philippines)

Corrections agreed:

Slide # 13 – deleted right competency profile

Slide # 14 – Good Personal Hygiene -add after visiting in 3rd bullet, thus:

After visiting the toilet

Slide # 16 – Proper Attire - add picture of short sleeves gown.

Slide # 17 – Attire design bullet 2 first line delete "use material that can screen particle optimally, thus;

Design of the attire should:
- no fiber materials
- no pocket at upper part of the waist.

Slide # 29 – closed doors and window - 3rd bullet add:

Screens must be installed on windows or any other openings to prevent entry of insects and rodents.

Slide # 34 – Rubbish Disposal - delete 3rd bullet

stating "no food wrapper should be thrown in garbage cans inside the production area.

Slide # 37 Sanitation Principles - 3rd bullet combined to 2nd bullet

Slide 38 – Cleaning Practices 3rd bullet change "When not in use, all cleaning compounds and sanitizers should be properly labeled and stored in a locked compartment, away from production and food storage areas to:

All cleaning compounds and sanitizers shall be properly labelled and stored away from production area.

AGENDA ITEM 6. Presentation and Finalization of Module # 6 Production Module authored and presented by Mr. Susilo Haryanto (Indonesia)

Corrections agreed:

Slide 16 key issues on starting packaging materials –6th Bullet Instead of Checking and recording of package department, change to packaging component, thus:

Checking and recording of packaging component

Slide 23 Verification of material delivery - add in 2nd bullet:
1.Identification of tag label should be placed on each weighed material;

Slide 24 Principles of water - 1st bullet change to:
It must be minimal drinking-water quality

Slide 27 Processing Guidance (1) - bullet F instead of Deviation from expected yield should be recorded and investigated prior to release of a batch, put in

Deviation from expected result should be recorded and investigated prior to release of a batch .

Slide 29 Bulk Quarantine Label - deleted the word HOLD filled in red color

Slide 31 Packaging Guidances - 1 Bullet 3 add in:

Line clearance in packaging area should be done.

Bullet 7 add in: "and in manual packaging operations."

Slide # 32 Packaging Guidances (2) - Bullet 10 Changed to:

Once Opened, should not be returned

Slide 44 Dry Product Handling -Bullet 2 changed to:

For materials used in very small quantity, an equipment with appropriate precision should be used.

Bullet 3: add when necessary, thus;

The room humidity of processing and filling activity should be controlled, when necessary.

Slide 59 Aerosol Storage Test -Corrections agreed:

Delete the slide but transfer to Stability as supplementary slide of QC

Slide #61 FG Principles - Transfer the last bullet to first bullet and correct grammar, thus:

While awaiting for approval, this finished product should be placed and kept under quarantine area at the finish product warehouse.

Slide # 66 Production Documents - corrections agreed:

Production documents of each cosmetic product should consist of:
Master Formula
Batch Manufacturing Record
Records for Quality Control

Slide # 74Related Hyperlink SOP - Last Bullet:

Add receiving

Slide # 75 related Hyperlink W.I. - add:

Master Formula
Record for QC

AGENDA ITEM 7. Presentation and Finalization of Module # 7 Quality Control Module authored by Stephanie Wong (Malaysia) and Ms. Eusebia Regodon (Philippines) presented in the meeting by Ms. Stephanie Wong.

Slide # 5 Objective -bullet 1 should be key elements not issues, thus:

To understand key elements in quality control.

Slide # 21 Finished Product Specification - bullet 3 changed to:

Description of finished product and its package details

Last bullet add: "manufacturing date or expiry date" thus:
Batch numbering requirement (including Manufacturing date or expiry date)

Slide 24 Quality Record Retention - 1st bullet changed to:

Master formula in batch manufacturing record shall be retained for the shelf life plus one year of the product.

Slide # 30 Sampling Plan - request for an attachment

Slide 34 Laboratory Data - last bullet changed to:

- There should be a written policy about averaging of numbers, cross-outs of mistakes, significant figures, leaving notebook pages or fill-in-the-blank entries empty, etc.

Slide 32 testing and Analysis - last bullet cancel last two-words operated properly change to:

- Where test is performed in-house, laboratory shall be available

Slide 35 Retain Sample - 3rd bullet delete the words "recommended to the end of product shelf life" and change to:

- Retain samples for each batch of finished products shall be retained at a defined period.
- 2nd bullet Add number 2 Thus:
  - 2 Full reexamination

AGENDA ITEM 8. Presentation and Finalization of Module # 8 Documentation Module authored by Ms. Hardaningsih (Indonesia) and Mr. Nguyen Van Loi (Vietnam). Presented in the meeting by Ms. Hardaningsih (Indonesia).

Corrections agreed:

Slide #6 Purpose - add 3rd bullet "The achievement of conformity and quality improvement

Slide # 12 Quality Standard Procedure add 6th bullet" reference to other relevant documents"

AGENDA ITEM 9. Presentation and Finalization of Module # 9 Internal Audit Module Authored and presented in the meeting by Mr. Lam Kok Seng (Singapore)

Corrections agreed:

Slide 7 Scope of IA (2) - bullet 2 change the word aspect to elements, thus:

Covering all elements of GMP including results of previous internal quality audit and any corrective and preventive actions (CAPA) taken

Slide # 27 site audit activities - delete 4th bullet

2nd to the last sentence add:

Focus, safety and quality of product

Slide 35 Closure - add "ensure CAPA identify the root cause", thus:
•Ensure CAPA identify the root cause and they are satisfactory, accomplished and documented

AGENDA ITEM 10. Presentation and Finalization of Module # 10 Storage of Products and Materials

Module Authored and presented in the meeting by Mr. Harris Lukmanto (Indonesia)

Corrections agreed
Slide 13 Temperature & humidity control (click hyperlink under numbers and locations monitoring)

-add humidity in the title

Title change to "Numbers and locations of monitoring points (temperature and humidity mapping)".

Bullet 1 delete the last sentence:

Bullet 2 correct the sentence to:

The Room should be well ventilated.

Slide 14 Storage and Temperature Requirements

Corrected the sentence: Storage condition must not compromise the safety and quality of the product

Slide 16 Storage Facilities (Click hyperlink under sufficient lighting)

Delete guidelines/ standard of lighting. May refer to any international standard.

Slide 33 Record Keeping - hyperlink to Documentation module for reference

Slide 39 Warehouse for starting materials - cancel weighing area.

Slide 54 Storage and Temperature Requirement (Click hyperlink under alarm system)

Add: Alarm system should comply to your local national regulations.

AGENDA ITEM 11 Presentation and Finalization of Module # 11 Contract Manufacturing
Module Authored and presented in the meeting by Ms. Catherine Clare Rivera (Philippines)

Corrections agreed:

Slide # 4 Scope - change to: This module will apply to contract giver and contract acceptor (cosmetic manufacturing facility and testing laboratory).

AGENDA ITEM 12 Presentation and Finalization of Module # 12 Product Complaints
Module authored and presented by: Mr. Lam Kok Seng (Singapore)

Corrections agreed:

Slide # 4 Introduction -Add the word distributor, thus:
This module is to assist the cosmetic manufacturer and distributor to establish a system to handle product complaints based on its quality, safety and efficacy

Slide # 7 Definition - add the word lacking in the 3rd bullet 2nd item, thus: lacking in quality, safety, and efficacy.

Slide 9 Product Complaint Principle -change review carefully to investigated, thus:

"All complaints and other information concerning potentially defective products must be carefully investigated according to written procedures."

Slide 10 Roles of Manufacturer - delete 3rd bullet: "to set a department to conduct"

Slide 16 Investigation Records - bullet 3 change to:

•Product type

Slide 17 Remedial Action - add a note below the slide:

" The person receiving complaint(s) will inform the responsible person or representative of the company to take necessary action."

Slide 21 Critical Defects - delete last bullet microbiological contamination

Slide 23 Minor Defect -under example, deleted the word notification and made a note on minor defects, thus:

1.Other defects are those defects which presents only minor risk to the customers. Any batch recall or product withdrawal would normally be initiated within a few days.

2.2.Examples of such defect are:

•Readily visible isolated packaging/closure faults

•Contamination which may cause spoilage or dirt and where there is minimal risk to the customers.3.3.Again this shows a less speedy response to the situation which is in balance with the level of risk for the customer.

Slide 25 Documentation - last bullet changed to:

In the event of product recall (product safety) the authority should be notified

AGENDA ITEM 13 Presentation and Finalization of Module # 13 Product Recall Module authored by Mr. Heng Huot (Cambodia) and presented by: Mr. Lam Kok Seng

Slide 4 Introduction - added the 2nd bullet of Product Complaints Introduction, thus:

•Any activity related to product recall must be aligned to the Post Marketing Surveillance Guideline

Slide 9 Definition (2) - delete bullet 2

Slide 11 Reasons for Recall - delete the word "known counterfeiting" in bullet 5

Slide 13 Basic Requirements - 1st bullet add the word "Preferably, " Responsible person is independent from seller or marketing

Slide 16 Level of Recall -add the word "up" for letter A,B,C and D

AGENDA ITEM 14 Presentation and Finalization of Module #14 for NRA How To Conduct Inspection. Module authored by and presented in the meeting by Pia Rose Belarmino(Philippines)

Slide # 3 Objectives - 3rd bullet changed to:

To assist the industry in preparation for the regulatory audit.

Slide # 27 Routine Inspection - last bullet deleted 3-5 years Thus:

Has not been inspected for the past years

Previous slide # 47 Classification of Findings -delete the whole slide of negative observations

Slide # 48 Classification of findings (Major) - change will not to may not:

Slide # 50 Conclusion - Change give suggestion and recommendation to:

make compliance rating and disclaimer

CONCLUSION

The meeting agreed the following:

Attach the hyperlink to duplicating topics, forms, pictures, examples and explanations. Further, the meeting adopted in principle the trainers notes below the slide presentations.

The meeting has agreed not to post to the website the 14th module which is how to conduct audit by the NRA until such time the terminologies and conditions are harmonized.

The meeting has adopted in principle the "GMP 14 Training Modules" and will endorse to the ACC meeting in Brunei on December 6-8 for official adoption.

Malaysia has accepted to host the first Regional Training to be held on November 30 – December 2.

ACKNOWLEDGEMENT

The chair and co-chairs expressed their appreciation to the good work everybody has given to finalize the 14 training modules.

The co-chair, ASEAN Officer, GMP Taskforce and the ACC Head of Delegates wished to extend heartfelt appreciation for the warm hospitality and very good organization the lead country has given.

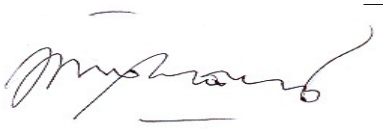
The Malaysia head of delegate, Anis Talib accepted and thanked the body for the very good cooperation and assistance each gave and congratulated all for the display of ASEAN Spirit that made possible to accomplish the finalization of the GMP 14 training modules a success.

Prepared by:

Jessica Plana
ASEAN Officer

Approved by:

Muhammad Lukmani Ibrahim
Chair – Lead country
Senior ASEAN Expert



Nuning Barwa
Co-Chair

Pia Rose Belarmino
Co-Chair

Adopted in principle the GMP 14 Training modules to be endorsed in the 5th ACC meeting in Brunei by the ACC Head Of Delegates

Chong Chee Kiong **Brunei**	Chheing Phana **Cambodia**	Hayatie Amal **Indonesia**
Vongtavanh Chiemsisourath **Laos**	Anis Talib **Malaysia**	Leticia Barbara Gutierrez **Philippines**
Marie Tham **Singapore**	Yupa Tiengthavaj **Thailand**	Ta Thi Phuc Chan **Vietnam**